

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

WILLIAM D. MCCLUSKEY, as Surviving Spouse and as Personal Representative of the Estate of Mary L. McCluskey, deceased, Plaintiff, v. MERCK & CO., INC., a foreign corporation; PHIZER INC., a Delaware Corporation; PHARMACIA CORPORATION, a Delaware Corporation; MONSANTO COMPANY, a Delaware Corporation; G. D. SEARLE, LLC, a Delaware Corporation; JAMES A. STEWART, an Individual; ANNA LEIGH WEBB, an Individual; TRAVIS TAYLOR, an Individual; Robert Vandelune, an Individual, et al, Defendant.

* * * * Case No. _____

ANSWER OF DEFENDANT MERCK & CO., INC.

COMES NOW, Defendant Merck & Co., Inc. ("Merck"), by its and through its undersigned attorneys, and hereby answers the Complaint ("Complaint") as follows:

Response to "PARTIES, JURISDICTION AND VENUE"

1. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the first four sentences of paragraph 1 of the Complaint, except admits that it manufactured, marketed and distributed the prescription medicine Vioxx until it voluntarily withdrew Vioxx from the worldwide market on September 30, 2004. Merck

denies each and every allegation directed at Merck in the fifth paragraph of paragraph 1 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that sentence.

2. Merck denies each and every allegation set forth in paragraph 2 of the Complaint, except admits that it is a New Jersey corporation with its principal place of business in New Jersey and that it is authorized to do business in Alabama. Merck further admits that it manufactured, marketed and distributed the prescription medicine Vioxx until it voluntarily withdrew Vioxx from the worldwide market on September 30, 2004, and that it marketed and distributed Vioxx in Alabama.

3. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information set forth in paragraphs 3 of the Complaint.

4. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information set forth in paragraphs 4 of the Complaint.

5. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information set forth in paragraphs 5 of the Complaint.

6. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information set forth in paragraph 6 of the Complaint.

7. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information set forth in paragraph 7 of the Complaint, except admits that Merck employed professional representatives to have product discussions concerning Vioxx with health

care professionals and that defendants James A. Stewart, Anna Leigh Webb and Cedric D. Anderson have been employed by Merck as professional representatives.

8. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the information set forth in paragraph 8 of the Complaint.

9. Merck objects to Plaintiff's use of the term "Defendants" to refer collectively to all named and/or fictitious defendants in this action and, to the extent that Plaintiff alleges that Merck is jointly and severally liable for damages for any alleged injury to his decedent, Merck denies the allegations set forth in this paragraph.

10. Merck denies to Plaintiff's allegations of agency and, to the extent that Plaintiff alleges that Merck is jointly and severally liable for damages for any alleged injury to his decedent, Merck denies the allegations set forth in this paragraph.

Response to "FACTUAL BACKGROUND"

11. Merck admits that Vioxx is part of a class of medications known as NSAID. Merck respectfully refers the Court to the relevant United States Food and Drug Administration ("FDA")-approved prescribing information for Vioxx for its indicated uses.

12. The allegations set forth in paragraph 12 of the Complaint are not directed at Merck, and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in that paragraph, except admits that the inhibition of the enzyme cyclooxygenase-1 ("COX-1") in patients taking traditional non-selective NSAIDs such as naproxen is believed to be associated with gastric damage and increased bleeding among patients taking such traditional non-selective NSAIDs.

13. Merck denies each and every allegation set forth in paragraph 13 of the Complaint and avers that the inhibition of the enzyme cyclooxygenase-1 (“COX-1”) in patients taking traditional non-selective NSAIDs such as naproxen is believed to be associated with gastric damage and increased bleeding among patients taking such traditional non-selective NSAIDs.

14. Merck denies each and every allegation set forth in paragraph 14 of the Complaint and avers that the inhibition of the enzyme cyclooxygenase-1 (“COX-1”) in patients taking traditional non-selective NSAIDs such as naproxen is believed to be associated with gastric damage and increased bleeding among patients taking such traditional non-selective NSAIDs.

15. The allegations set forth in paragraph 15 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in paragraph 15 of the Complaint except admits that COX-2 is constitutively expressed in the kidneys, the brain, and the reproductive tract, although its precise impact on the functioning of these organs is not fully known.

16. The allegations set forth in paragraph 16 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in paragraph 16 of the Complaint.

17. Merck denies each and every allegation set forth in paragraph 17 of the Complaint except admits that Vioxx is part of a class of drugs known as NSAIDs and that Merck manufactured, marketed, and distributed the prescription medicine Vioxx which reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2).

18. The allegations set forth in paragraph 18 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in paragraph 18 of the Complaint.

19. The allegations set forth in paragraph 19 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in paragraph 19 of the Complaint.

20. The allegations set forth in paragraph 20 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in paragraph 20 of the Complaint.

21. The allegations set forth in paragraph 21 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck admits the allegations set forth in paragraph 21 of the Complaint.

Response to "The VIOXX® Timeline

22. Merck admits the allegations of Paragraph 22 of the Complaint.

23. Merck denies each and every allegation set forth in paragraph 23 of the Complaint.

24. Merck denies each and every allegation set forth in paragraph 24 of the Complaint.

25. Merck denies each and every allegation set forth in paragraph 25 of the Complaint.

26. Merck denies each and every allegation set forth in paragraph 26 of the Complaint, except that it admits that the FDA review referenced in this paragraph exists, and respectfully refers the Court to said review for its actual language and full text.

27. Merck denies each and every allegation set forth in paragraph 27 of the Complaint.

28. Merck denies each and every allegation set forth in paragraph 28 of the Complaint except admits that it sought and, in May 1999 received approval from the United States Food and Drug Administration (“FDA”) to manufacture and market the prescription medicine Vioxx as safe and effective for certain indicated uses in a manner consistent with the relevant FDA-approved prescribing information, and respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its full text and for Vioxx’s indicated uses.

29. Merck denies each and every allegation set forth in paragraph 29 of the Complaint.

30. Merck denies each and every allegation set forth in paragraph 30 of the Complaint except admits that Peter Holt conducted certain audio conferences pertaining to Vioxx.

31. Merck denies each and every allegation contained in paragraph 31 of the Complaint and avers that plaintiff purports to characterize correspondence from the FDA’s Division of Drug Marketing, Advertising and Communications (“DDMAC”), and respectfully refers the Court to the referenced correspondence for its actual language and full text.

32. Merck denies each and every allegation contained in paragraph 32 of the Complaint except admits that it received a letter from DDMAC dated July 16, 1999 and respectfully refers the Court to the referenced letter for its actual language and full text.

33. Merck denies each and every allegation set forth in paragraph 33 of the Complaint and respectfully further refers the Court to the study referenced therein for its actual language.

34. Merck denies each and every allegation set forth in paragraph 34 of the Complaint.

35. Merck denies each and every allegation set forth in paragraph 35 of the Complaint except admits that Merck received a letter from Spencer Salis of DDMAC in December 1999 and respectfully refers the Court to that letter for its actual language and full text.

36. Merck denies each and every allegation set forth in paragraph 36 of the Complaint except admits the referenced study exists and respectfully refers the Court to the referenced study for its actual language and full text.

37. Merck denies each and every allegation set forth in paragraph 37 of the Complaint except admits the VIGOR study involving Vioxx exists and respectfully refers the Court to the referenced study for its actual conclusions and full text.

38. Merck denies each and every allegation set forth in paragraph 38 of the Complaint.

39. Merck denies each and every allegation set forth in paragraph 39 of the Complaint.

40. Merck denies each and every allegation set forth in paragraph 40 of the Complaint.

41. Merck denies each and every allegation set forth in paragraph 41 of the Complaint.

42. Merck denies each and every allegation set forth in paragraph 42 of the Complaint and respectfully refers the Court to the article referenced in the New England Journal of Medicine for its actual conclusions and full text.

43. Merck denies each and every allegation set forth in paragraph 43 of the Complaint, except admits that on February 8, 2001, the FDA's Arthritis Advisory Committee met and that the Vioxx label was discussed. Merck respectfully refers the court to the transcript of the meeting for the actual language and full text of any recommendations.

44. Merck denies each and every allegation set forth in paragraph 44 of the Complaint, except admits the referenced article exists, and respectfully refers the Court to the referenced article for its actual language and full text.

45. Merck denies each and every allegation set forth in paragraph 45 of the Complaint.

46. Merck denies each and every allegation set forth in paragraph 46 of the Complaint, except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001, from which plaintiff purports to quote, and respectfully refers the Court to the referenced letter for its actual language and full text.

47. Merck denies each and every allegation set forth in paragraph 47 of the Complaint, except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001, and respectfully refers the Court to the referenced letter for its actual language and full text.

48. Merck denies each and every allegation set forth in paragraph 48 of the Complaint, except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001, from which plaintiff purports to quote, and respectfully refers the Court to the referenced letter for its actual language and full text.

49. Merck denies each and every allegation set forth in paragraph 49 of the Complaint, except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001, from which plaintiff purports to quote, and respectfully refers the Court to the referenced letter for its actual language and full text.

50. Merck denies each and every allegation set forth in paragraph 50 of the Complaint, except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001, from which plaintiff purports to quote, and respectfully refers the Court to the referenced letter for its actual language and full text.

51. Merck denies each and every allegation set forth in paragraph 51 of the Complaint, except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001, which plaintiff purports to characterize, and respectfully refers the Court to the referenced letter for its actual language and full text.

52. Merck denies each and every allegation contained in paragraph 452 of the Complaint, except admits the referenced "Dear Healthcare Provider" letter exists.

53. Merck denies each and every allegation contained in paragraph 53 of the Complaint.

54. Merck denies each and every allegation set forth in paragraph 54 of the Complaint, except admits that an FDA review of the sNDA exists. Merck respectfully refers the court to said review for the actual language and full text.

55. Merck denies each and every allegation contained in paragraph 55 of the Complaint.

56. Merck denies each and every allegation contained in paragraph 56 of the Complaint.

57. Merck denies each and every allegation set forth in paragraph 57 of the Complaint, except admits that in April 2002 the FDA approved certain labeling changes for Vioxx, and respectfully refers the Court to the relevant FDA-approved prescribing information for its actual language and full text.

58. Merck denies each and every allegation contained in paragraph 58 of the Complaint, except admits the referenced study exists, and respectfully refers the Court to the referenced study for its actual language and full text.

59. Merck denies each and every allegation contained in paragraph 59 of the Complaint.

60. Merck denies each and every allegation contained in paragraph 60 of the Complaint, except admits the referenced presentation occurred, and respectfully refers the Court to the referenced presentation for its actual language and full text.

61. Merck denies each and every allegations contained in paragraph 61 of the Complaint, except admits the referenced press release exists, and respectfully refers the Court to the referenced press release for its actual language and full text.

62. Merck denies each and every allegation set forth in paragraph 62 of the Complaint and except admits that on September 27, 2004, Merck contacted the FDA and advised the FDA that the APPROVe clinical trial had been halted and respectfully refers the Court to the referenced study for its actual language and full text..

63. Merck denies each and every allegation set forth in paragraph 63 of the Complaint and avers that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking Vioxx compared with those taking placebo. Merck further avers that given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx from the worldwide market best served the interests of patients.

64. Merck denies each and every allegation set forth in paragraph 64 of the Complaint and avers that on November 5, 2004, an article was published online in The Lancet entitled "Risk of Cardiovascular Events and Rofecoxib: Cumulative Meta-analysis" and respectfully refers the Court to that article for its actual language and full text.

65. Merck denies each and every allegation set forth in paragraph 65 of the Complaint.

66. Merck denies each and every allegation set forth in paragraph 66 of the Complaint.

67. Merck denies each and every allegation set forth in paragraph 67 of the Complaint, except admits that it has estimated that there were approximately 105 million prescriptions for Vioxx written in the United States from May 1999 through August 2004.

68. Merck denies each and every allegation set forth in paragraph 68 of the Complaint.

Response to "The CELEBREX® Timeline

69. The allegations set forth in paragraph 69 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

70. The allegations set forth in paragraph 70 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

71. The allegations set forth in paragraph 71 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required,

Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

72. The allegations set forth in paragraph 72 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

73. The allegations set forth in paragraph 73 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

74. The allegations set forth in paragraph 74 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

75. The allegations set forth in paragraph 75 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

76. The allegations set forth in paragraph 76 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required,

Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

77. Merck denies each and every allegation set forth in paragraph 77 of the Complaint and respectfully further refers the Court to the study referenced therein for its actual language.

78. Merck denies each and every allegation set forth in paragraph 78 of the Complaint.

79. Merck denies each and every allegation set forth in paragraph 79 of the Complaint, except admits the VIGOR study involving Vioxx exists, and respectfully refers the Court to the referenced study for its actual conclusions and full text.

80. The allegations set forth in paragraph 80 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

81. The allegations set forth in paragraph 81 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

82. The allegations set forth in paragraph 82 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

83. Merck denies each and every allegation set forth in paragraph 83 of the Complaint, except admits the referenced article exists.

84. Merck denies each and every allegation set forth in paragraph 84 of the Complaint, except admits the referenced article exists, and respectfully refers the Court to the referenced article for its actual conclusions and full text.

85. Merck denies each and every allegation directed at Merck in paragraph 85 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

86. The allegations set forth in paragraph 86 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

87. The allegations set forth in paragraph 87 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

88. The allegations set forth in paragraph 88 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

89. Merck denies each and every allegation set forth in paragraph 89 of the Complaint, except admits that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking Vioxx compared with those taking placebo. Merck further avers that given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx from the worldwide market best served the interests of patients.

90. The allegations set forth in paragraph 90 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

91. Merck denies each and every allegation set forth in paragraph 91 of the Complaint, except admits the referenced editorial exists, and respectfully refers the Court to the referenced editorial for its actual language and full text.

92. The allegations set forth in paragraph 92 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

93. The allegations set forth in paragraph 93 of the Complaint are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in that paragraph.

Response to "Fraudulent Concealment, Tolling and Estoppel

94. The allegations set forth in paragraph 94 are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in that paragraph, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

95. Merck denies each and every allegation directed at Merck in paragraph 95 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

96. Merck denies each and every allegation directed at Merck in paragraph 96 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

97. Merck denies each and every allegation directed at Merck in paragraph 97 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

98. The allegations set forth in paragraph 98 are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in that paragraph, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

Response to "CAUSES OF ACTION"

COUNT I – STRICT LIABILITY AND/OR NEGLIGENCE PER SE

(Against Merck and Pfizer)

Restatement of Torts (Second) §402A

Restatement of Torts (Third): Prod. Liab. §6

99. With respect to the allegations set forth in paragraph 99 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 98 of this Answer with the same force and effect as though set forth here in full.

100. Merck denies each and every allegation directed at Merck in paragraph 100 of the Complaint, except admits that it manufactured, marketed and distributed the prescription medicine Vioxx until it voluntarily withdrew Vioxx from the worldwide market on September 30, 2004, and that it marketed and distributed Vioxx in Alabama. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

101. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in paragraph 101 of the Complaint.

102. Merck denies each and every allegation directed at Merck in paragraph 102 of the Complaint, including subparagraphs a. through d., and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

COUNT II – NEGLIGENCE
(Against Merck and Pfizer)

103. With respect to the allegations set forth in paragraph 103 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 102 of this Answer with the same force and effect as though set forth here in full.

104. The allegations set forth in paragraph 104 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 104 of the Complaint, and respectfully refers the Court to the relevant legal standard, including any conflict of laws rules. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

105. The allegations set forth in paragraph 105 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 104 of the Complaint, and respectfully refers the Court to the relevant legal standard, including any conflict of laws rules. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

106. Merck denies each and every allegation directed at Merck in paragraph 106 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

107. Merck denies each and every allegation directed at Merck in paragraph 107 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

108. Merck denies each and every allegation directed at Merck in paragraph 102 of the Complaint, including subparagraphs a. through i., and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

109. Merck denies each and every allegation directed at Merck in paragraph 109 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

110. Merck denies each and every allegation directed at Merck in paragraph 110 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

111. Merck denies each and every allegation directed at Merck in paragraph 111 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

COUNT III – FAILURE TO WARN
(Against Merck and Pfizer)
Restatement of Torts (Second) §388
or
Restatement of Torts (Third): Prod. Liab. §6

112. With respect to the allegations set forth in paragraph 111 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 102 of this Answer with the same force and effect as though set forth here in full.

113. The allegations set forth in paragraph 113 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 104 of the Complaint, and respectfully refers the Court to the relevant legal standard, including any conflict of laws rules. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

114. Merck denies each and every allegation directed at Merck in paragraph 114 of the Complaint, including subparagraphs a. through b., and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

115. The allegations set forth in paragraph 115 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 104 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

116. Merck denies each and every allegation directed at Merck in paragraph 116 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

117. The allegations set forth in paragraph 117 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 104 of the Complaint, and respectfully refers the Court to the relevant legal standard, including any conflict of laws rules.

Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

118. Merck denies each and every allegation directed at Merck in paragraph 118 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

**COUNT IV – FRAUD AND FALSES ADVERTISING
(Against Merck and Pfizer)**

119. With respect to the allegations set forth in paragraph 118 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 102 of this Answer with the same force and effect as though set forth here in full.

120. The allegations set forth in paragraph 120 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 104 of the Complaint, and respectfully refers the Court to the relevant legal standard, including any conflict of laws rules. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

121. Merck denies each and every allegation directed at Merck in paragraph 121 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

122. Merck denies each and every allegation directed at Merck in paragraph 122 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

123. Merck denies each and every allegation directed at Merck in paragraph 123 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

124. Merck denies each and every allegation directed at Merck in paragraph 124 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

125. Merck denies each and every allegation directed at Merck in paragraph 125 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

126. Merck denies each and every allegation directed at Merck in paragraph 126 of the Complaint, including subparagraphs c. through g., and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

127. Merck denies each and every allegation directed at Merck in paragraph 127 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

128. Merck denies each and every allegation directed at Merck in paragraph 128 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

129. Merck denies each and every allegation directed at Merck in paragraph 129 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

130. Merck denies each and every allegation directed at Merck in paragraph 130 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

131. Merck denies each and every allegation directed at Merck in paragraph 131 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

132. Merck denies each and every allegation directed at Merck in paragraph 132 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

133. Merck denies each and every allegation directed at Merck in paragraph 133 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

134. Merck denies each and every allegation directed at Merck in paragraph 134 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

135. The allegations set forth in paragraph 135 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 135 of the Complaint, and denies

knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

136. Merck denies each and every allegation directed at Merck in paragraph 136 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

COUNT V – MISREPRESENTATION BY SELLER OF CHATTEL
(Against Merck and Pfizer)
Restatement of Torts (Second) §402B
Restatement of Torts (Third): Prod. Liab. §9

137. With respect to the allegations set forth in paragraph 137 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 102 of this Answer with the same force and effect as though set forth here in full.

138. Merck denies each and every allegation directed at Merck in paragraph 138 of the Complaint, except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx until Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

139. Merck denies each and every allegation directed at Merck in paragraph 139 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

140. Merck denies each and every allegation directed at Merck in paragraph 140 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

141. Merck denies each and every allegation directed at Merck in paragraph 141 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

COUNT VI – BREACH OF EXPRESS AND IMPLIED WARRANTY
(Against Merck and Pfizer)

142. With respect to the allegations set forth in paragraph 142 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 102 of this Answer with the same force and effect as though set forth here in full.

143. Merck denies each and every allegation directed at Merck in paragraph 143 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

144. Merck denies each and every allegation directed at Merck in paragraph 144 of the Complaint, including subparagraphs a. through e., and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

145. The allegations set forth in paragraph 145 are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 145 of the Complaint, and denies knowledge or

information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

146. Merck denies each and every allegation directed at Merck in paragraph 146 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

147. Merck denies each and every allegation directed at Merck in paragraph 147 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

148. Merck denies each and every allegation directed at Merck in paragraph 148 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

149. Merck denies each and every allegation directed at Merck in paragraph 1498 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

COUNT VII – WRONGFUL DEATH

150. With respect to the allegations set forth in paragraph 150 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 149 of this Answer with the same force and effect as though set forth here in full.

151. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in paragraph 151 of the Complaint.

152. Merck denies each and every allegation directed at Merck in paragraph 152 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

153. Merck denies each and every allegation directed at Merck in paragraph 153 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

154. Merck denies each and every allegation directed at Merck in paragraph 154 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

For response to Plaintiff's demand for relief, Merck denies that Plaintiff sustained, or is entitled to, compensatory or punitive damages, or other recovery, fees, costs, expenses, or other relief.

**COUNT VIII – CONSUMER PROTECTION ACT
(Against Merck and Pfizer)**

155. With respect to the allegations set forth in paragraph 155 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 154 of this Answer with the same force and effect as though set forth here in full.

156. Merck denies each and every allegation directed at Merck in paragraph 156 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

157. Merck denies each and every allegation directed at Merck in paragraph 157 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

158. Merck denies each and every allegation directed at Merck in paragraph 158 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

159. The allegations set forth in paragraph 159 are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation set forth in that paragraph.

160. Merck denies each and every allegation directed at Merck in paragraph 160 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

161. Merck denies that Plaintiff is entitled to attorney's fees or costs.

COUNT IX

**(Claims against James A. Stewart, Anna Leigh Webb, Cedric D. Anderson,
Travis Taylor and Robert Vandelune Sales representative Defendants)**

162. With respect to the allegations set forth in paragraph 162 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 161 of this Answer with the same force and effect as though set forth here in full.

163. – 189. The allegations set forth in these paragraphs are the subject of Motions to Dismiss which are being filed on behalf of the individual defendants due to the fact that they

have been fraudulently joined in this action. In addition, Merck denies each and every allegation contained in these paragraphs.

COUNT X – DAMAGES
(Against All Defendants)

190. With respect to the allegations set forth in paragraph 190 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 189 of this Answer with the same force and effect as though set forth here in full.

191. Merck denies each and every allegation directed at Merck in paragraph 191 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

192. Merck denies each and every allegation directed at Merck in paragraph 192 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

193. Merck denies each and every allegation directed at Merck in paragraph 193 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

194. The allegations set forth in paragraph 194 of the Complaint are legal conclusions to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation directed at Merck in paragraph 194 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

COUNT XI – PUNITIVE DAMAGES
(Against Merck and Pfizer)

195. With respect to the allegations set forth in paragraph 195 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 194 of this Answer with the same force and effect as though set forth here in full.

196. Merck denies each and every allegation directed at Merck in paragraph 196 of the Complaint, except admits that plaintiff purports to seek punitive damages, but denies there is any legal or factual basis for the relief sought. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

197. Merck denies each and every allegation directed at Merck in paragraph 197 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

198. Merck denies each and every allegation directed at Merck in paragraph 198 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

199. Merck denies each and every allegation directed at Merck in paragraph 199 of the Complaint, except admits that plaintiff purports to seek punitive damages, but denies there is any legal or factual basis for the relief sought. Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

COUNT XII – LOSS OF CONSORTIUM
(Against All Defendants)

200. With respect to the allegations set forth in paragraph 200 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 199 of this Answer with the same force and effect as though set forth here in full.

201. Merck denies each and every allegation directed at Merck in paragraph 201 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

202. Merck denies each and every allegation directed at Merck in paragraph 202 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

203. Merck denies each and every allegation directed at Merck in paragraph 203 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed at Merck in that paragraph.

Response to “PRAYER FOR RELIEF”

In regard to Plaintiff’s Prayer for Relief, Merck admits that Plaintiff brings this action and purports to seek monetary damages but denies that there is any legal or factual basis for such relief. Merck denies that Plaintiff sustained, or is entitled to, compensatory or punitive damages, or other recovery, fees, costs, expenses, or other relief.

GENERAL MATTERS

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to

assert any and all pertinent liability defenses ascertained through further investigation and discovery in this action.

Merck incorporates any applicable defense or other defense asserted by any other defendant in this action. Merck will rely on all defenses that may become available during discovery or trial.

GENERAL AFFIRMATIVE DEFENSES

1. The Plaintiff's claims may be time-barred, in whole or in part, under applicable statutes of limitations, statutes of repose, or are otherwise untimely.
2. The Complaint fails to state a claim upon which relief can be granted.
3. The claims of the Plaintiff may be barred, in whole or in part, from recovery because Plaintiff have made statements or taken actions that preclude Plaintiff from asserting claims or constitute a waiver of Plaintiff's claims.
4. The claims of the Plaintiff may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.
5. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, voluntary payment, waiver or statutory and regulatory compliance.
6. If Plaintiff have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.
7. To the extent that Plaintiff assert claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

8. To the extent that Plaintiff assert claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

9. If Plaintiff have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

10. If Plaintiff have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

11. If Plaintiff have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff' misuse or abuse of Vioxx.

12. If Plaintiff have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff' pre-existing and unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

13. To the extent Plaintiff have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

14. To the extent Plaintiff are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under Alabama law.

15. Plaintiff' claims of fraud are barred by reason of Plaintiff' failure to allege the circumstances constituting fraud with particularity, as required by Federal Rule of Civil Procedure 9(b) and Alabama Rule of Civil Procedure 9(b).

16. Plaintiff' claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

17. Plaintiff' claims are barred in whole or in part by the First Amendment.

18. Plaintiff' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

19. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

20. This case may be more appropriately brought in a different venue.

21. Venue in this case may be improper.

22. The claims of Plaintiff may be barred, in whole or in part, from recovery because, in this or other courts, Plaintiff have brought actions and received judgments on parts of some or all claims asserted herein.

23. The claims of Plaintiff may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

24. The claims of Plaintiff may be barred, in whole or in part, from recovery by release as to Plaintiff' claims.

25. The claims of Plaintiff may be barred, in whole and in part, by the doctrine of laches.

26. The claims of Plaintiff are barred, in whole or in part, by Plaintiff' failure to mitigate damages.

27. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

28. The claims of Plaintiff may be barred, in whole or in part, from recovery, due to spoliation of evidence.

29. The claims of Plaintiff may be barred, in whole or in part, by the governing state laws.

30. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

31. Plaintiff have not sustained any injury or damages compensable at law.

32. Merck reserves its right to dismiss the Complaint and seek further relief for Plaintiff' failure to provide it with due process of law.

33. Plaintiff' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

34. Plaintiff' claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation

Plaintiff allege to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

35. Plaintiff' claims are barred under Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

36. Plaintiff' claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

37. To the extent that Plaintiff seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

38. To the extent that Plaintiff seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of punitive damages is barred.

39. Plaintiff' demand for punitive damages is barred because Vioxx and its labeling were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

40. To the extent Plaintiff make a claim for punitive damages, Merck asserts that such Plaintiff have not complied with statutory requirements to recover punitive damages.

41. To the extent Plaintiff' claims invoke punitive damages, such claims violate the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments of the Constitution of the United States, on the following grounds:

(a) It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant

upon a plaintiff satisfying a burden of proof which is less than the “beyond a reasonable doubt” burden of proof required in criminal cases;

- (b) The procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;
- (c) The procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution. *See Pacific Mut. Life Ins. Co. v. Haslip*, 111 S. Ct. 1032, 113 L. Ed. 2d 1.
- (d) The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (e) The procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts and, thus, violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;
- (f) The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and
- (g) The retroactive application of punitive damages violates the contracts clause of the United States Constitution, Article I, Section 10.
- (h) Plaintiff’s claims for punitive damages violate the due process clause of Article I, Section 13 of the Constitution of Alabama, on the following grounds:
 - (1) It is a violation of the due process clause to impose punitive damages which are penal in nature, upon a civil defendant upon a plaintiff satisfying a burden of proof less than the “beyond a reasonable doubt” burden of proof required in criminal cases;
 - (2) The procedures pursuant to which punitive damages are awarded fail to provide a limit on the amount of the award against

these defendants;

(3) The procedures pursuant to which punitive damages are awarded are unconstitutionally vague;

(4) The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages; and

(5) The award of the punitive damages in this case constituted a deprivation of property without due process of law.

- (i) Plaintiff's attempt to impose punitive or extra-contractual damages on this defendant, on the basis of vicarious liability for the conduct of others, violates the Fifth and Fourteenth Amendments of the United States Constitution.
- (j) The award of punitive damages to the Plaintiff in this action would constitute a deprivation of property without due process of law required under the Fifth and Fourteenth Amendments of the United States Constitution.
- (k) The procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine in violation of Article I, Section 15 of the Constitution of Alabama.
- (l) The award of punitive damages against these defendants in this action would violate the prohibition against laws that impair the obligations of contracts in violation of Article I, Section 22 of the Constitution of Alabama.
- (m) The procedures pursuant to which punitive damages are awarded are vague and unpredictable such that they violate the defendant's right to defend himself pursuant to Article I, Section 10 of the Constitution of Alabama.
- (n) The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the amount established by the legislature under Ala. Code, Section 27-1-17 (1975) in violation of the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution and Article I, Section 6 of the Constitution of Alabama.

42. Plaintiff' Complaint seeks to make Merck liable for punitive damages. The United States Supreme Court has reversed the Alabama Supreme Court in the case styled *BMW of North America, Inc. v. Gore*, 116 S. Ct. 1589 (1996), on the issue of punitive damages. Merck adopts by reference the defenses, criteria, limitations, and standards mandated by the United States Supreme Court decision in that case and in *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003); and any subsequent applicable decisions.

43. Merck affirmatively pleads that any punitive damages that the Plaintiff may recover in this case should be capped in keeping with Alabama Code § 6-11-21, as amended in 1999 (Act. No. 99-358) and in the spirit of the Alabama Supreme Court's decision in *Oliver v. Towns*, 738 So. 2d 798 (Ala. 1999).

44. The demand for punitive damages in the instant case is subject to the limitations established by the Alabama legislature and set forth in Ala. Code § 6-11-21 (1975). Merck adopts by reference the defenses, criteria, limitations, and standards mandated by this Alabama statute. The Alabama Supreme Court's action in abolishing the legislatively created cap on punitive damages was unconstitutional and is without effect. Under the Constitutions of the United States and the State of Alabama, the Alabama Supreme Court cannot abolish the cap created by the legislature on punitive damages through this judicial decision. *See Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415, 114 S. Ct. 2331, 2340 n.9 (1994).

45. Merck avers that the punitive damage cap set out in Ala. Code § 6-11-21 (1975) applies to the instant case. *See Horton Homes, Inc. v. Brooks*, 832 So. 2d 44 (Ala. 2001).

46. Merck avers that the punitive damages award is subject to limitation based on harm that has occurred and harm that is likely to occur. *See TXO Prod. Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711 (1993).

47. Merck avers that the method of imposing punitive damages violates Amendment 328, Section 6.11 of the Constitution of Alabama, which prohibits the use of a procedural rule to abridge, enlarge, or modify the substantive right of any party. *See Leonard v. Terminix Int'l Co.*, 854 So. 2d 529 (Ala. 2002).

48. The imposition of punitive damages is an act of policy making on the part of the judiciary, in violation of Article III, Section 43 of the Constitution of Alabama.

49. Merck adopts the terms of any applicable legislative act or Alabama Supreme Court decision which now or hereafter precludes punitive damages or limits the amount of punitive damages that can be recovered in an action at law in Alabama.

50. To the extent that Plaintiff relied upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and lack of privity and because the alleged warranties were disclaimed.

51. Plaintiff' claims are barred by the Statute of Frauds.

52. Plaintiff cannot show reasonable reliance as a matter of law.

53. Plaintiff' claims for negligence per se are barred on the grounds that such claims are not cognizable against Merck in this action.

54. To the extent Plaintiff seek to recover only economic loss in tort, Plaintiff' claims are barred by the economic loss doctrine.

55. Merck denies that it was guilty of any actionable negligence, denies that Plaintiff were injured thereby, and denies the existence of any proximate cause to the alleged damages.

56. If Plaintiff have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

57. Plaintiff, knowing the nature and properties of Vioxx, consented to use Vioxx, and accordingly Merck cannot be held liable.

58. To the extent there were any risks associated with the use of Vioxx which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings.

59. The public interest and benefit in the availability of Vioxx preclude liability of Merck for any risks, if any, resulting from such activities, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff' claims, if it is determined that there is a risk inherent in Vioxx, then such risk, if any, is outweighed by the benefits of Vioxx.

60. Merck denies that Vioxx was unreasonably dangerous, defective, or that Vioxx created any liability under the Alabama Extended Manufacturer's Liability Doctrine.

61. Plaintiff' claims based on breach of warranty and negligence are subsumed by the Alabama Extended Manufacturer's Liability Doctrine.

62. To the extent that Plaintiff' claims and allegations against Merck relate to mere puffery that is not misleading to a reasonable person, such claims are not actionable.

63. With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

64. Plaintiff' claims are barred, in whole or in part, because Plaintiff lack capacity and/or standing to bring such claims.

65. This case may be more appropriately brought in a different venue, and the claims of the Plaintiff are improperly joined and therefore should be severed.

66. Merck pleads the general issue and denies that it was liable or responsible for any alleged damages to Plaintiff.

67. Merck hereby gives notice that it intends to rely upon such other defenses as may become available or appear during discovery proceeding in this case or that are included in the master answer to be filed in the Multidistrict Litigation proceeding before Judge Fallon of the Eastern District of Louisiana. Merck hereby reserves the right to amend its answer to assert any such defense.

68. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery in this action.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable costs and disbursements with such and other and further relief that the Court may deem just and proper together.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

s/ Richard B. Garrett

Richard B. Garrett

Bar Number: (ASB-0782-A29R)
Mike Brock
Bar Number: (ASB-5280-B61R)
F. Chadwick Morris
Bar Number: (ASB-8504-S75F)

RUSHTON, STAKELY, JOHNSTON
& GARRETT, P.A.
Post Office box 270
Montgomery, Alabama 36101-0270
Telephone: 334/206-3100
Fax: 334/263-4157
E-mail: rbg@rsjg.com
rcb@rsjg.com
fcm@rsjg.com

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on February 2, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Andy D. Birchfield, Jr., Esquire
Benjamin L. Locklar, Esquire
Beasley, Allen, Crow, Methvin,
Portis & Miles, P. C.
P. O. Box 4160
Montgomery, Alabama 36103-4160

s/Richard B. Garrett
Of Counsel